

REMARKS

Claims 1, 3 and 5 to 19 as amended above are present for purposes of prosecution.

As per the interview of March 29, 2004, Applicants affirm their election of Group I Claims 1 to 19 drawn to compounds of the formula of Claim 1 where X and Q represents C;

A represents  $-(CH_2)_x^2-O-(CH_2)_x^3-$ ;

the 5-membered ring between B and A represents 1,2,4-oxadiazole or 1,2,3-triazole, and Y represents COOH;

pharmaceutical compositions containing these compounds; and  
a method of using these compounds.

The Examiner objects to the Abstract because it is too long. Applicants have now amended the abstract so that it is in compliance with the Rules of Practice.

Claims 1 to 19 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement.

The Examiner specifically mentions that the specification on the first page states that "the instant compounds modulate blood glucose levels, triglyceride levels, insulin levels and non-esterified fatty acid levels." The Examiner questions the term "modulation" as including both increases and decreases in the above levels.

It would be apparent that one skilled in the art would expect that since the compounds of the invention are useful in the treatment of diabetes and obesity as well as hyperglycemia, hyperinsulinemia, hyperlipidemia, obesity and atherosclerosis, that the term "modulate" refers to reducing blood glucose levels, triglyceride levels, fatty acid levels, and in increasing insulin levels.

With respect to Y, the Examiner contends that "there is not even a single compound exemplified where Y is other than -COOH group or any ester."

Please note page 23, Scheme 3, where ester compound 11 is shown;  
page 24, Scheme 5, where ester compound 58 is shown;  
page 33, Scheme 17, where ester compound 58 is shown;  
page 34, Scheme 18, where ester compound 58 is shown;  
page 34, Scheme 19, where ester compound 60 is shown; and  
page 36, Scheme 22, where ester compound 68 is shown.

In addition please note the working Examples where innumerable ester compounds of the invention are disclosed.

In addition, please note page 46 of the Specification lines 3 to 6 where phosphorus acid esters are discussed as well as prodrug esters.

The Examiner further contends that "there is no mention of any mechanism such as enzyme inhibition, receptor agonist/antagonist activity, etc."

Applicants have disclosed how to make the compounds of the invention as well as how to use them. Applicants have disclosed at page 8 of the Specification that the compounds claimed are useful for treating diabetes and related diseases as well as obesity. Applicants have disclosed dosages and dosage forms at pages 64 and 65 of the Specification. In fact, Applicants have disclosed everything necessary to enable one skilled in the art to carry out and practice the present invention without undue experimentation. The Examiner has not advanced any arguments or cited references which would lead one skilled in the art to doubt Applicants' teachings of how to make and how to use the invention claimed.

The state of the prior art is illustrated by U.S. Patent No. 6,653,314 to Cheng et al. and U.S. Patent No. 6,506,781 to Cobb et al. as well as the references cited in the Information Disclosure Statement as filed as well as the references cited in these prior art references, many of which teach compounds useful for treating diabetes. These references further buttress Applicants' position that the Examiner has no reason to doubt Applicants' disclosure on how to use the compounds claimed.

With regard to Claims 15 and 16, the Examiner contends that there are no working examples present to show how the instant compounds will have utility in treating all the disease conditions set out.

As set out above, Applicants have fully complied with the disclosure requirements of how to make and how to use their invention so that one skilled in the art may practice the invention claimed without undue experimentation.

In view of the foregoing, it is submitted that Claims 1 to 19 are in compliance with 35 U.S.C. §112, first paragraph.

Claims 1 to 12 and 14 to 19 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner contends that:

"in independent claim 1, the terms –prodrug ester and stereoisomers – are indefinite since it is not clear which prodrug and stereoisomer is being referred here and how are they prepared. There is not even a single example of either prodrug or stereoisomer in the specification. The applicants are suggested to delete these items."

Please note pages 46 and 47 of the Specification wherein there is a full disclosure of prodrug esters and stereoisomers. In addition, please note the working Examples for the preparation of various stereoisomers of compounds of the invention.

The Examiner further maintains that

"in independent claim 1, the applicants mention that groups  $-(CH_2)_x$ ,  $(CH_2)_{x1}$  etc. may be optionally substituted with 1, 2 or 3 substituents. However, these substituents are not defined."

Applicants have now amended the claims to define the noted substituents as based on the disclosure at page 40, lines 4 to 15 and thereafter.

The Examiner further contends that

"in claim 1, the value of variable  $R^3$  defined as heteroaryl, cycloheteroalkyl is indefinite since the size of the ring, number and types of heteroatoms present in the ring are not defined."

Claim 1 has been amended to include the size of the ring, and number and types of heteroatoms present in the ring as based on the disclosure at pages 44 and 45.

The Examiner further contents that

"in claim 15, the term ---related diseases--- is indefinite since these diseases are not defined and furthermore, it is not clear how they are related."

Claim 15 has been amended to remove the objected to subject matter.

The Examiner indicates that

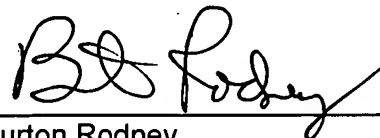
"Claims 1-12 and 14-19 are objected as containing non-elected subject matter."

In view of the amendments to the Claims as set out above, it is believed that Claims 1 to 12 and 14 to 19 no longer contain non-elected subject matter.

Applicants note that the Examiner has indicated that the compounds directed to the elected group I are allowable over the prior art.

In view of the foregoing, it is submitted that Claims 1, 3 and 5 to 19 overcome all formal objections and cover allowable subject matter and thus are in condition for allowance.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Burton Rodney", is written over a horizontal line.

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